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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/830,176      | 04/23/2001  | Joseph P. Dougherty  | 13257-00040         | 2969             |

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LICATA & TYRRELL P.C.  
66 EAST MAIN STREET  
MARLTON, NJ 08053

EXAMINER

WOITACH, JOSEPH T

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1632

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/830,176

Applicant(s)

DOUGHERTY ET AL.

Examiner

Joseph T. Woitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 7 and 8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7 and 8 is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

This application is 371 national stage filing of PCT/US99/25477, filed October 29, 1999, which claims benefit to provisional application 60/106,533, filed October 31, 1998.

Applicants' amendment filed November 25, 2005, has been received and entered. Claims 1 and 2 have been amended. Claims 4-6 and 9-19 have been cancelled. Claims 1-3, 7 and 8 are pending.

### ***Election/Restrictions***

Applicant's election of Group I, was acknowledged. The election was treated as an election without traverse because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, (MPEP § 818.03(a)). No new arguments are presented

Claims 4-6 and 9-19 drawn to nonelected inventions have been canceled.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claims 1-3, 7 and 8 are under examination as they are drawn to the elected invention of a composition comprising transduced myeloid committed stem cells and a method of use to express an exogenous nucleic acid sequence.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 2 (and dependent claim 3) rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn.

In view of the amendment to claim 1, and upon review of the portions of the specification noted by Applicants, Examiner agrees that the instant specification provides literal and figurative support for the instantly claimed invention. For example, pages 20-21 specifically recites “LPS-simulated, T cell-depleted spleen cells”, and though there is no specific recitation that the composition contains myeloid-committed stem cells in this passage (as recited in the claims), this was present in the original claim, as well as being supported by the working examples provided in the specification as being present in such a composition.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 stand rejected under 35 U.S.C. 102(b) as being anticipated by Freas-Lutz DL *et al.* (Exp Hematol. 1994 Aug;22(9):857-65).

Claims 1 and 2 stand rejected under 35 U.S.C. 102(b) as being anticipated by Migita *et al.* (PNAS 92:12075-12079).

Applicants summarize the requirements of making a proper rejection under 35 USC 102, citing MPEP 2131. Applicants summarize the general teaching of the references and the requirements of the claims, arguing the claimed invention has the feature of being “myeloid-committed, *i.e.*, of the myeloid lineage” (amendment page 7-citing page 13 of the specification) and LPS-stimulated. See Applicants’ amendment pages 6-8. Applicants arguments have been fully considered, and found persuasive in part.

Applicants do not contest that the cells taught in Freas-Lutz DL *et al.* and Migita *et al.* do not contain myeloid committed cells, rather only that the cells would be different without indicating any relative functional difference or characteristic the artisan would use for such a distinction. Initially, with respect to LPS-stimulation, in view of the art of record it does not appear that this would material affect the claimed myeloid-committed stem cell, rather in a mixed culture, *i.e.* cells isolated from the spleen, this provides the stimulus for increasing the number of such cells in a given composition. Again, the present specification does not provide any specific definition for what is encompassed by the term myeloid committed stem cell, and therefore it has been given its broadest reasonable interpretation. In this case, cells of Freas-Lutz DL *et al.* and Migita *et al.* meet this functional requirement for their ability to differentiate into a myeloid lineage.

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Examiner would acknowledge that the process of isolating cells in the cited references and that presently disclosed are not the same, however would maintain that neither the specification nor the claims provides for more than the functional limitation that the myeloid committed stem cell is capable of differentiating into myeloid lineages. Given the breadth of the claims in light of the teaching of the specification. Again, as noted previously, Freas-Lutz *et al.* teach the use of retroviral vectors for the transfection and expression of an exogenous nucleic acid sequence encoding glucocerebrosidase into the isolated cells. Further, the various retroviral constructs taught have various promoters to analyze the expression and activity of glucocerebrosidase, including the use of the phosphoglycerate gene promoter which is expressed in macrophages (a differentiated myeloid cell). Since the instant specification does not specifically define what a myeloid committed stem cell is, and in the broadest reasonable interpretation of being any cell with a restricted ability to become a differentiated cell of the myeloid lineage. Similarly, Migita *et al.* teach the use of retroviral vectors for the transfection and expression of an exogenous nucleic acid sequence encoding glucocerebrosidase. One of the cell types used by Migita *et al.* are human CD34+ cells (see top of page 12078, for example) which represent a population of cells which have the capacity to differentiate into various cells of the myeloid lineage. Also, these cells are not T-cells, and thus represent a composition which do not have T-cells.

As discussed above, the instant specification does not specifically define what a myeloid committed stem cell is, and is being given the broadest reasonable interpretation of being any cell with a restricted ability to become a differentiated cell of the myeloid lineage. The CD34+

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cells taught by Migita *et al.* meet this interpretation of a myeloid committed progenitor cell because it is capable of myeloid specific differentiation.

### ***Conclusion***

Claims 7 and 8 are allowed.

While myeloid committed cells were known to be present in the spleen as early as 1982 in the prior art (see Magli *et al.* Nature, 1982) or Reisner, US Patent 5,652,373 (in particular paragraphs 28-34 and 45-made of record in this action). These cells represented a non-renewable and short lived source of such a cell type as summarized in the instant specification (page 2, lines 25-33). There is insufficient motivation in the art of record to use the spleen as a source of myeloid committed stem cells in methods of expressing myeloid specific proteins.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

*Joe Woitach*  
*AV 1632*